IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Jonathon M. Graff, et al.	Group Art Unit: 1642
Serial No.: 10/771,620	Examiner: Peter J. Reddig
Filed: February 4, 2004	Atty. Dkt. No.: UNI919/4-8US
For: MARKERS FOR DIAGNOSING AND TREATING BREAST AND OVARIAN CANCER	Confirmation No.: 9412

PRE-APPEAL BRIEF REQUEST FOR A PANEL REVIEW

VIA EFS-WEB
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper is filed concurrently with a Notice of Appeal in response to a Final Office Action of July 10, 2007.

REASONS FOR REQUESTING REVIEW

The Examiner has improperly rejected Claim 1 as lacking written description for the term "full length complement of SEQ ID NO:3 or SEQ ID NO:4" and under 112, 1st for the step of detecting a "significant" increase in expression level as an indication of breast cancer.

A. Status of the Claims

Claims 1, 3, 5, 7-9, 66-69, and 71-72 are pending.

B. Prosecution After Final Rejection

Appellants filed a Response to the Final Office Action on September 10, 2007. A telephone interview was conducted with Appellants' representatives on September 12, 2007 to discuss the final rejections and Appellants' response. During the interview, the Examiners and Appellants' representatives agreed to several amendments that would place the claims in better condition for allowance or appeal. It was apparent during the interview that one of the Examiners

was using an electronic copy of the application and doing a "word search" and that decisions on compliance with the written description requirement were based solely on whether the word in a claim could be found in the specification. Although Appellants' representatives expressed that this is not a proper examination for written description, the amendments were agreed to in order to progress the case to allowance.

A supplemental response to the Final Rejection was filed on September 14, 2007 including the amendments as discussed in the telephone interview of September 12, 2007.

A second telephone interview was conducted on October 9, 2007 in which the Examiners expressed additional concerns with the claims and Appellants' representative agreed to further claim amendments in order to progress the case to allowance. It was also stated that the Examiner would issue an Advisory Action and that the amendments discussed in the interview could be filed after mailing of the Advisory Action.

An Advisory Action was issued on October 15, 2007.

A second supplemental response to the Final Action was mailed on November 13, 2007 containing the amendments as discussed in the second interview.

After submission of the amendments in the second supplemental response a third telephone interview was conducted with Examiner Reddig and the undersigned Appellants' representative. Examiner Reddig stated that the claims would be allowable if the term "full length complement of SEQ ID NO:3 or SEQ ID NO:4" were canceled from Claim 1 because of an alleged lack of written description and further that Claim 1 be amended such that the step of detecting a "significant" increase be changed to detecting a 2-fold increase to be diagnostic of breast cancer. Appellants' representative did not agree to these improper rejections and thus files this appeal.

C. Remarks

1. **An examination of the written description requirement requires an analysis of whether one of skill in the art would understand the inventors to have had possession of the claimed invention at the time of filing.**

The Federal Circuit has recently re-stated this requirement for the written description requirement:

A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. See *Union Oil Co. v. Atl. Richfield Co.*, 208 F.3d 989, 997 [54 USPQ2d 1227] (Fed.

Cir. 2000). That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. *In re GPAC Inc.*, 57 F.3d 1573, 1579 [35 USPQ2d 1116] (Fed. Cir. 1995). Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation. *Lizard Tech, Inc. v. Earth Resource Mapping* 424 F3d 1336, 76 USPQ2d 1724, 1732 (Fed. Cir. 2005)

The Federal Circuit has further clarified the requirement for biological macromolecules:

It is settled law that there is no per se rule that an adequate written description of a biological macromolecule must contain a recitation of known structure *Falkner v. Inglis* 448 F.3d 1357, 1366, 79 USPQ2d 1001, 1007 (Fed. Cir. 2006)

The specification and claims are in full compliance with the written description requirement because one of skill in the art would understand that the inventors had possession of the full length complements of the disclosed nucleic acid sequences.

The rejection of Claim 1 for alleged lack of written description is improperly based on a misapplication of the written description requirement to the present specification and claims. Claim 1 is drawn to a method of diagnosing breast cancer by detection of increased expression of a marker identified by the inventors. The claim is drawn to a method in which samples are assayed to determine the level of expression of the marker having the nucleic acid sequence of SEQ ID NO:3 or SEQ ID NO:4 or the full length complement of those sequences and comparing the expression level to the expression level of the same sequences in a normal tissue. The rejection is based on the ground that the complementary sequences are not listed in the specification.

Appellants submit that the specification provides more than adequate written description for the full length complement of the disclosed nucleic acid sequences. As is well known, when a nucleic acid sequence is known, as in the present application, generating a complement sequence would not require undue experimentation, or any experimentation at all in most cases. It is common practice in the art to identify a gene sequence using only a single strand as was done in the subject application, but certainly one of skill would understand the double stranded nature of genes or coding sequences of genes, and that recitation of both strands is unnecessary.

The specification provides more than adequate description of the use of the complementary sequences. The specification at [0053] discusses hybridization of sample nucleic acids to their complementary sequences bound to solid supports; and detecting the sample

nucleic acids using PT at [0053], a technique that necessarily requires double stranded molecules to be detected. Additionally, in discussing kits, the specification at [0078] states, "Suitable reagents for specifically binding with a nucleic acid (e.g. a genomic DNA, an mRNA, a spliced mRNA, a cDNA, or the like) include complementary nucleic acids." Thus, even though the nucleic acid sequence of the complementary molecules are not listed, the specification provides more than adequate support for the use of those sequences as would be understood by one of skill in the art.

Based on these brief comments, Appellants respectfully request the Panel to find in favor of the Appellants that the present claims fully comply with the written description requirement, and further affirm the standard by which the written description requirement is examined.

2. **The requirement that Claim 1 be amended to include the limitation that a two-fold increase in expression of the claimed nucleic acid sequences is necessary to be diagnostic of breast cancer is an erroneous attempt to limit the claims to what is described as a preferred embodiment in the specification.**

As stated above, the Examiner has stated in a telephone interview that Claim 1 would be allowable if the element "a significant increase in expression" is amended to "a two-fold increase in expression." The Specification at [0072] states that the preferred methods would be able to detect any significant increase in expression. Although the subsequent paragraph states that certain preferred methods would include detection of two or more-fold increases, Claim 1 should not be limited to a preferred embodiment of a two-fold increase. It is well known that a physician, upon viewing the expression levels of the newly disclosed marker would consider any statistically significant increase in expression of the marker to be important in making a diagnosis of cancer.

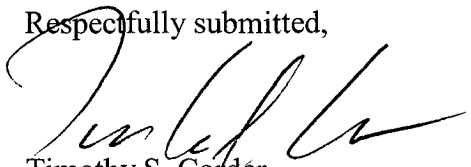
The present rejection completely ignores the spirit of the claim, which is to use the presence of increased expression of the newly disclosed marker as a diagnostic aid for breast cancer. Any statistically significant increase would be useful to a physician or diagnostician in making such a diagnosis. Such an increase, which could be less than or more than a two-fold increase over the normal or control tissue would fall within the claimed invention and should not be excluded without strong evidence or a well reasoned explanation, neither of which has been provided.

Appellants assert, therefore, that the rejection of Claim 1 for use of the term "a significant increase" is improper, and respectfully request that the rejection be overturned.

D. Conclusion

In light of the foregoing, Appellants respectfully request withdrawal of all rejections and immediate allowance of the existing claims.

Respectfully submitted,



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